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SIPDIS

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TAGS: [ETRD](#) [KIPR](#) [TU](#)
SUBJECT: GOT's Unclear Message on Data Exclusivity

Ref: (A) State 322108 (B) Ankara 6847

Summary

¶11. (SBU) At the December Economic Partnership Commission meeting, the Turkish Health Ministry and Foreign Trade Undersecretariat took seemingly contradictory positions on data exclusivity protection for pharmaceuticals. A followup meeting with the Health Undersecretary reinforced our impression that there is no GOT interagency consensus on this issue, and that any GOT move toward data exclusivity in early 2004 is likely to be unsatisfactory. The Ambassador is raising this issue at the political level (septel), but we also request Washington's assistance in following up in the near future, including by sending an expert-level delegation and, possibly, a Minister-level letter on this issue. End Summary.

¶12. (SBU) At the December Economic Partnership Commission (EPC) meeting, Health Ministry Pharmaceuticals Director General Hayriye Mihcak presented a paper stating that new legislation on data exclusivity protection for pharmaceuticals would be enacted in the first half of 2004, but did not specify whether and how long a transition period for implementation would be included in the law. At the EPC's private sector session the following day, Tevfik Mengü, Foreign Trade's Director General for Agreements, appeared to contradict the Health Ministry in saying that Turkey believed it was already satisfying its TRIPS obligations in this area.

¶13. (SBU) Following up on the EPC discussions, Econ Counselor requested clarification in a meeting with Health Ministry Undersecretary Necdet Unuvar and Pharmaceuticals Director General Hayriye Mihcak on December 12. Mihcak stated that the Ministry intended to implement a regulation (not new legislation) on data exclusivity in the second quarter of 2004, but added that the GOT was evaluating "international best practices" in this area in formulating its regulation. She also noted that the Ministry was not the only state body which would have to approve the regulation, and implied that there may not be an interagency consensus on data exclusivity as yet. Mihcak disputed Foreign Trade's contention that Turkey was already in full compliance with TRIPS Article 39.3. Unuvar and Mihcak raised concerns about the potential costs of implementation which range from several million dollars (according to the research-based companies) and several billion (according to their generic competition).

¶14. (SBU) Econ Counselor responded that the generic producers had a strong incentive to frighten the GOT with inflated cost estimates and contended that their figures were far from accurate. He emphasized that data exclusivity protection was long overdue under the TRIPS Agreement (not to mention Turkey's EU Customs Union Agreement), that the current Turkish pharmaceutical regime allowed local companies to "steal" from U.S. companies, and that the USG was losing patience on this issue. Turkey would likely be elevated in our Special 301 Watch Lists in the absence of swift corrective action, which had to include moving to TRIPS-compliant data exclusivity quickly. Econ Counselor noted that the EPC delegations committed to a followup meeting at the expert level on intellectual property and other issues. Unuvar and Mihcak responded that they looked forward to these expert-level discussions.

15. (SBU) EU MISSION ECONOMIC COUNSELOR OSKAR BENEDIKT CONTACTED ECONOFF ON DECEMBER 16 TO REPORT THAT BRUSSELS HAD DECIDED NOT TO PURSUE A JOINT DEMARCHE WITH THE USG ON DATA EXCLUSIVITY (REF A) UNTIL IT HAS COMPLETED ITS TRADE BARRIERS REVIEW (TBR) OF TURKEY. HOWEVER, HE LEFT OPEN THE POSSIBILITY THAT SOME JOINT ACTION COULD BE CONSIDERED AFTER THE TBR IS COMPLETED.

RECOMMENDED ACTIONS

16. (SBU) TO GET THE MOST MILEAGE OUT OF THE SPECIAL 301 PROCESS, WE SHOULD USE ALL NEAR-TERM OPPORTUNITIES TO ENGAGE THE GOT ON IPR ISSUES. FOR EXAMPLE, THE AMBASSADOR RAISED THE ISSUE FORCEFULLY WITH MINISTERS BABACAN AND UNAKITAN ON DECEMBER 17 (SEPTEL). AT THE EPC, WE AGREED TO PRESENT THE TURKS WITH AN ANALYSIS OF AREAS IN WHICH WE BELIEVE TRIPS IS NOT BEING IMPLEMENTED. BOTH SIDES AGREED TO MEET AT THE EXPERT LEVEL EARLY IN 2004 ON IPR AND OTHER TRADE/INVESTMENT ISSUES. EMBASSY URGES WASHINGTON AGENCIES TO PROPOSE A DELEGATION AND DATES AS EARLY AS POSSIBLE. WE ALSO REITERATE OUR SUGGESTION THAT WASHINGTON OUTLINE OUR CONCERNS IN WRITING, SUCH AS THROUGH A JOINT LETTER FROM USTR ZOELLICK AND COMMERCE SECRETARY EVANS TO STATE MINISTER TUZMEN (REF B). WASHINGTON AGENCIES MIGHT ALSO THINK ABOUT ASKING EU AUTHORITIES TO RECONSIDER THEIR POSITION ON A JOINT DEMARCHE. EDELMAN